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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,771	03/19/2002	Kaneyoshi Kato	2648 US0P	2340

23115 7590 01/29/2004

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,771

Applicant(s)

KATO ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-17,28,35-39 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 18-20,22,23,25,26,34 and 40-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claims 1-45 are pending in this application.

Election/Restrictions

Applicants' election of Group XI subject matter along with species of Example # 95 with traverse is noted. In the traverse, applicants suggested groups I, VI, XI, XVI be examined together because they share the common technical, namely, Ar' being either aryl or heteroaryl and R1 and R2 either forming or not forming a ring. Applicants' arguments are found persuasive, and therefore, these groups will be examined together. Because of the changes proposed by applicants, the claims in the previous requirement were regrouped as follows:

Group I, claim(s) 1-17, drawn to a melanin-concentrating hormone antagonist of formula I.

Group II, claim(s) 18-26, 34, and 40-44, drawn to the compounds of formula I wherein Ar¹ is a cyclic group, X' is CONR^{8c}, Ar' is the first formula, Y and R2 do not form a ring.

Group III, claims 18-26, 28, and 45, drawn to the compounds of formula I not included in Group II.

Group IV, claims 35-39, drawn to a method of using the compounds.

1. During a telephone conversation with Ms. Elaine Ramesh on 01/21/04 a provisional election was made with traverse to prosecute the invention of group II, claims 18-26, 34, and 40-44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-17, 28, 35-39, and 45 are withdrawn from further

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consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20, 22, 23, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1). The use of "a nitrogen-containing hetero ring" in the definition of R1 and 2 taken together to form a ring is unclear to the array of heteroatoms, size of the rings, as

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well as nature of atoms as ring members. See *In re Wiggins* 179 USPQ 421 for certain terminology regarding heterocyclic ring systems.

2). The meaning of the phrase "which may have substituents" throughout claims 18-20, 22-23, and 25-26 is unclear as to the nature and number of substituent(s) intended.

3). Claims 18-20, 22, 23, 25, and 26 is vague and indefinite in that the metes and bounds of the word "spacer" are unknown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 18-20, 22-23, and 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Fink et al. (US 6,197,798). Fink teaches the compounds and composition of the instant invention (see Compounds (z), col. 33, (aa), col. 35, (bk), col. 51, (bl), col. 53, (bq), col. 55, (ci), col. 63, (gh), col. 113).

Claims 18 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Werbel et al., Chem Abstract 73: 109549. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compounds having RN 26419-24-9 and 28785-26-4.

Claims 18-20, 22-23, 25-26, and 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Preregaard et al., Chem Abstract 124: 232261. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compounds having RN 174776-05-7 and 174776-06-8.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, 22-23, 34, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6,197,798). The reference teaches a generic group of

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compounds which embraces applicant's instantly claimed compounds. See formula I, Col. 1 wherein R₆ is N(R_a)C(O)N(R_b)(R_c), wherein R_b and R_c are independently hydrogen, alkyl, cycloalkyl, aryl, or heterocyclyl, or R_b and R_c together represent lower alkylene or lower alkylene interrupted by O, S, or N, etc. The compounds are taught to be useful as pharmaceutical agents for treating obesity, etc. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claim Objections

Claims 18-19, 22, 25, and 34 are objected to as being an improper Markush grouping. The recited compounds, while possessing a common utility, present a

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variable core and, thus, the Markush groups represented by the term where X' is - C(O)NH- and X' is other than is -C(O)NH-, and Ar' is other the first formula in claim 18 have variably different definitions, render the claims improper.

Deletion of non-elected subject matter would overcome this objection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Liu whose telephone number is 703 3065814.

The examiner can normally be reached on 8:30-6:00.

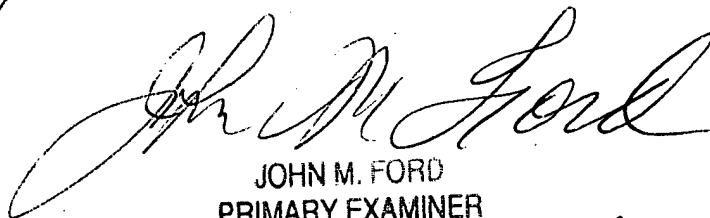
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703 308 4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4556 for regular communications and 703 3084734 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 358-1235.

hl
January 22, 2004



Mukund Shah
Supervisory Patent Examiner
Art Unit 1624



JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT

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